UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

PFIZER INC.,	:	
Plaintiff,	:	
	:	
-against-	:	**1:14-cv-4659 (ALC)**
	:	
MCNEIL-PPC, INC.,	:	**OPINION & ORDER**
	:	
Defendant.	:	

ANDREW L. CARTER, JR., United States District Judge:

I. INTRODUCTION

A twenty-six-year-old consent decree bans Pfizer from running advertisements stating that Advil, a Pfizer product, and Tylenol, a McNeil-PPC product, induce the same side effects in a consumer's stomach. Over two decades after signing the decree, Pfizer ran advertisements for infants' Advil equating its stomach side effects with Tylenol products. When McNeil objected, Pfizer filed this complaint seeking a declaratory judgment that the consent decree does not apply to pediatric Advil products. McNeil moved to dismiss the complaint for failure to allege a justiciable controversy under the Declaratory Judgment Act. For the reasons stated below, the Court denies the motion to dismiss.

II. BACKGROUND

This suit is the latest salvo in a long-running battle between the makers of Tylenol and Advil. Thirty years ago, defendant McNeil and plaintiff Pfizer's predecessor, American Home Products ("AHP"), sued each other over claims of false advertising related to the marketing of Advil and Tylenol. See Am. Home Products Corp. v. Johnson & Johnson, 654 F. Supp. 568 (S.D.N.Y. 1987) ("Advil I"); McNeilab, Inc. v. Am. Home Products Corp., 675 F. Supp. 819 (S.D.N.Y. 1987) aff'd, 848 F.2d 34 (2d Cir. 1988) ("Advil II"). Advil I considered print and

television advertisements from both parties that made comparative claims about Tylenol and Advil's side effects and safety. Advil I, 654 F. Supp. at 571. Advil II concerned a narrower set of Advil advertisements alone that featured an actor who stated, in words or substance, "Like Tylenol, Advil doesn't upset my stomach." Am. Home Products Corp., 654 F. Supp. at 820.

Both suits were ultimately resolved by entries of consent judgments that enjoined each party from making certain claims about Tylenol and Advil in future advertising. At issue in this suit is the consent judgment from Advil II ("Advil II Order"). The Advil II Order enjoined AHP and "all those in privity with it" (namely, Pfizer) from "stating in words or substance in any advertisement that ADVIL is 'like TYLENOL' in the respect of adverse effects on the stomach . . . ." Advil II Order ¶ 1.

At the time that Advil I and Advil II were litigated, neither Children's nor Infants' Advil were on the market. Amended Complaint ¶ 7. AHP therefore presented no evidence in those suits as to the products' safety and suitability for children and infants. Id. ¶ 10. Subsequent to signing the Advil II Order and in connection with its application for federal approval of pediatric ibuprofen products, AHP conducted a study titled the Children's Analgesic Medicine Project ("CAMP Study"). Id. ¶ 41. The CAMP study compared the safety of ibuprofen and acetaminophen in over 41,000 children suffering from fever and pain, over 14,000 of whom were infants under the age of two. Id.

In October 2013, twenty-four years after signing the Advil II Order, Pfizer ran an advertisement in several professional medical journals stating that ibuprofen, the active ingredient in Infants' Advil, has a "comparable incidence of digestive system adverse events overall" when compared to acetaminophen, the active ingredient in Infants' Tylenol. Id., Exh. B at ¶ 12. The advertisement cited two medical journal articles that analyzed the results of the

CAMP Study. Id. ¶ 43. Shortly thereafter, in November 2013, McNeil's Senior Counsel sent Pfizer's Chief Counsel a cease-and-desist letter requesting that it immediately retract the advertisement on the grounds that it ran afoul of the Advil II Order. Id. Exh. C at ¶ 13. In response, Pfizer retracted the advertisement but also sent McNeil a letter in which it contested the applicability of the Advil II Order to Infants' Advil because "the Court did not and could not have considered evidence of ibuprofen's safety profile in this population and it is not reasonable to conclude that the Court would have intended for the [Advil II] Order to apply to pediatric products." Id. Exh. D at ¶ 15.

In June 2014, Pfizer brought this suit seeking a declaratory judgment that the Advil II Order does not apply to Children's Advil, Infants' Advil, or other ibuprofen products approved for use in people under the age of 12. Id. ¶ 15. Pfizer is prepared to rerun the October 2013 advertisement for Infants' Advil should the Court decide in its favor and it intends to run additional advertisements "containing similar comparability claims for both Infants' Advil and Children's Advil in the future." Id. ¶¶ 15, 48.

III. DISCUSSION

A. Legal Standard

To survive a motion to dismiss under Fed.R.Civ.P. 12(b)(6), a complaint must contain "sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009) (quoting Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570 (2007)). On a motion to dismiss, the court accepts the plaintiff's allegations as true. Kassner v. 2nd Ave. Delicatessen Inc., 496 F.3d 229, 237 (2d Cir.2007). Further, the court must "draw all reasonable inferences in favor of the plaintiff," id. (citing Fernandez v. Chertoff, 471 F.3d 45, 51 (2d Cir.2006)). However, the court need not accept allegations that are merely

conclusions of law. Kassner, 496 F.3d at 237 (a complaint is inadequate if it "merely offers labels and conclusions or a formulaic recitation of the elements of a cause of action"). Ultimately, on a motion to dismiss "[t]he appropriate inquiry is not whether a plaintiff is likely to prevail, but whether he is entitled to offer evidence to support his claims." Fernandez, 471 F.3d at 51 (internal quotation marks and citation omitted).

B. Discussion

a. Jurisdiction exists to enforce the terms of the Advil II Order.

Paragraph three of the Advil II Order states that "[t]he Court shall retain jurisdiction for purposes of enforcing the injunctions contained in this Consent Final Judgment." Accordingly, this Court has jurisdiction to decide the matter before it.

b. Analysis

i. Pfizer alleges a justiciable controversy under the Declaratory Judgment Act.

The Declaratory Judgment Act permits a district court to "declare the rights and other legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought." 28 U.S.C. § 2201(a). Ideally, a judgment under the Act clarifies the legality of future actions a party may take rather than forcing it to incur liability for past actions already taken. Put otherwise, "the very purpose of the Declaratory Judgment Act" is to eliminate the Sophie's choice a plaintiff faces "between abandoning his rights or risking prosecution." MedImmune, Inc. v. Genentech, Inc., 549 U.S. 118, 129 (2007).

However, a court may only issue a declaratory judgment in relation to "a case of actual controversy within its jurisdiction . . . ." 28 U.S.C. § 2201(a). No bright line test exists for determining whether a case is one "of actual controversy." MedImmune, 549 U.S. at 127. Instead, "the question in each case is whether the facts alleged, under all the circumstances, show

that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." Id. (citing Maryland Casualty Co. v. Pacific Coal & Oil Co., 312 U.S. 270, 273 (1941)). Under this analysis, "the threat of future litigation remains relevant in determining whether an actual controversy exists." Nike, Inc. v. Already, LLC, 663 F.3d 89, 95-96 (2d Cir. 2011) aff'd, 133 S. Ct. 721 (2013). Cease-and-desist letters therefore commonly feature in sufficiently immediate and concrete disputes under the Declaratory Judgment Act, no doubt because they indicate a not insubstantial threat of future litigation. See e.g. Venugopal v. Sharadha Terry Products, Ltd., 2009 WL 1468462, at *4 (W.D.N.Y. May 22, 2009); Russian Standard Vodka (USA), Inc., 523 F. Supp. 2d 376, 383 (S.D.N.Y. 2007).

The parties do not dispute the existence of a substantial controversy: whether the Advil II Order includes pediatric Advil products within its sweep. McNeil does argue, however, that Pfizer's complaint is insufficiently immediate and real. It paints Pfizer as merely prepared to rerun the pulled 2013 Infants' Advil advertisement pending a decision in its favor by this Court—proof, McNeil contends, that Pfizer has no immediate plans to rerun it. Further, the fact that Pfizer intends to make similar comparability claims in Children's Advil advertisements at some point in the future is too vague to merit a declaratory judgment here, because the claims in the Infants' Advil advertisement depended on statistical findings pertinent to infants alone. Any advertisement for Children's Advil must necessarily be based on other, unidentified studies. Indeed, by filing such an abstract complaint, Pfizer prevents McNeil from pursuing a counter-claim declaratory judgment action. At heart, then, McNeil argues that to survive a motion to dismiss, Pfizer must plead the specifics of its advertising campaign for each product. In the case of Infant's Advil, that means specifying when the advertisements will rerun. In the case of

Children's Advil, that means specifying where, when, and under what form any advertisements will appear, as well as to whom they will be directed, and upon what studies they will be based.

A review of post-MedImmune cases in this circuit makes apparent that such an exacting degree of specificity is not required to survive a motion to dismiss a request for declaratory judgment. Instead, courts in this circuit find a controversy of sufficient immediacy and reality under the Declaratory Judgment Act where a plaintiff has engaged in meaningful preparation of a product or campaign whose imminent roll-out may expose her to liability. See e.g. Gelmart Indus., Inc. v. Eveready Battery Co., 2014 WL 1512036, at *5 (S.D.N.Y. Apr. 15, 2014) (plaintiff "alleged that it solicited retailers, designed branding materials, is capable of commencing manufacture of products within weeks, and was 'poised' to commence a product launch before [defendant] asserted infringement"); Diamonds.net LLC v. Idex Online, Ltd., 590 F. Supp. 2d 593, 599 (S.D.N.Y. 2008) (plaintiff "plans to roll out its upgraded system in the United States in the near future"); Russian Standard Vodka, 523 F. Supp. at 383 ("[P]laintiffs allege that they have an advertising campaign centered on highlighting the distinction between" their product and the defendant's).

Pfizer has done more than engage in meaningful preparation of Infants' Advil advertisements with comparative claims; it has already rolled them out. As for Children's Advil, Pfizer "is fully prepared" to run advertisements comparing Advil and Tylenol in terms of stomach safety. AC ¶ 48. It is of little import under the Declaratory Judgment Act whether Pfizer runs those advertisements in a medical journal or a parenting magazine or whether the claims therein are based on the CAMP study or other research. Nor is it necessary for Pfizer to allege the exact date in which the Children's Advil advertisements will run. Indeed, it is impossible for Pfizer to do so, because it awaits this Court's decision on the legality of such an advertisement.

Id. ¶ 48. Finally, McNeil's complaint that it cannot countersue for its own declaratory judgment due to Pfizer's vague allegations rings hollow. Indeed, by arguing in its motion to dismiss that its own reading of the Advil II Order is correct as a matter of law, McNeil effectively asks the Court for a declaratory judgment in its favor.

The threat of future litigation on this issue also supports Pfizer's case against dismissal. McNeil's Senior Counsel sent a cease-and-desist letter directly to Pfizer's Chief Counsel in response to the advertisement for Infants' Advil. That letter asserted that the advertisement's claims were both false and "contrary to the letter and spirit" of the Advil II Order and included a request "that Pfizer immediately retract" any advertisements claiming comparability between ibuprofen and acetaminophen in terms of adverse gastrointestinal effects. Amended Complaint, Exh. C. It also requested direct follow-up between the opposing counsels within two weeks of the letter's writing. Id. McNeil's response letter, also drafted by counsel, contested Pfizer's assertion of false advertising and the applicability of the Advil II Order to the comparative claims. It also explicitly "reserve[d] all our rights with regard" to the latter issue. Id., Exh. D.

Even if the cease-and-desist letters alone were not enough to indicate a threat of future litigation, the Court also considers the context in which this complaint was filed: the "endless war between two titans of the over-the-counter . . . drug industry." Advil I, 654 F. Supp. at 571. As the Advil I court put it, "[s]mall nations have fought for their very survival with less resources and resourcefulness than these antagonists have brought to their epic struggle for primacy in the analgesic field." Id. at 571-72. The threat of future litigation on this issue between these two parties therefore looms large.

In light of McNeil's meaningful preparation and imminent roll-out of advertisements with comparative safety claims and the threat of future litigation in this matter, the Court

concludes that Pfizer has alleged a sufficiently immediate and concrete controversy to warrant a declaratory judgment.

ii. The Court exercises its discretion to accept jurisdiction in this case.

Even if Pfizer's claim is both immediate and concrete, the plain language of the Declaratory Judgment Act states only that a court "*may* declare the rights and other legal relations of any interested party seeking such declaration." 28 U.S.C. § 2201(a) (emphasis added). Accepting jurisdiction of a claim that otherwise satisfies the Declaratory Judgment Act's requirements is therefore an inherently discretionary matter. Dow Jones & Co. v. Harrods Ltd., 346 F.3d 357, 359 (2d Cir. 2003). The Second Circuit uses a five-factor test to weigh this discretionary decision:

> [1] whether the judgment will serve a useful purpose in clarifying or settling the legal issues involved; ... [2] whether a judgment would finalize the controversy and offer relief from uncertainty[;] ... [3] whether the proposed remedy is being used merely for procedural fencing or a race to res judicata; [4] whether the use of a declaratory judgment would increase friction between sovereign legal systems or improperly encroach on the domain of a state or foreign court; and [5] whether there is a better or more effective remedy.
>
> New York v. Solvent Chem. Co., 664 F.3d 22, 26 (2d Cir. 2011).

McNeil's cease-and-desist request relied on two arguments: that claims of comparative stomach safety between Tylenol and Advil were (1) false and (2) barred by the Advil II Order. Under factors one and two of the Second Circuit's test, the declaratory judgment sought by Pfizer would at least clarify and resolve the second legal issue raised by McNeil: whether the Advil II Order applies to pediatric Advil products. On the other hand, a declaratory judgment as to that narrow issue alone would likely not finalize the controversy over the larger issue of whether comparative claims between pediatric Advil and Tylenol are otherwise impermissible because they are false.

Yet precisely because that issue would remain unsettled, the proposed judgment here is not accurately characterized as what factor three calls a "race to res judicata." Any declaratory judgment awarded here would not bar the substantively distinct claim by McNeil that the comparative statement in question, though not barred by the Advil II Order, is nonetheless false under applicable federal or state laws. See Advil I, 654 F.Supp. at 572 (making claims of falsity or unfair competition under the Lanham Act, New York General Business Law, and common law). The third factor therefore weighs in Pfizer's favor.

The fourth factor is not implicated by the facts of this case. As to the fifth factor, McNeil argues that Pfizer's proper remedy is under Rule 60(b) of the Federal Rules of Civil Procedure, which allows for relief from a final order upon presentation of "newly discovered evidence," if applying the judgment "prospectively is no longer equitable," or for "any other reason that justifies relief." If Pfizer wishes to change the terms of the Advil II Order based on the CAMP study, it should present such evidence in a motion to modify or set aside the order. But Pfizer's contention is not that the Order should be modified. Rather, it is that the Order as is does not implicate pediatric Advil. Rule 60(b) is not a proper avenue to vindicate that claim. So the fifth factor also weighs in favor of exercising discretion to accept jurisdiction.

Accordingly, under the five-factor test used in the Second Circuit, the Court exercises its discretion to accept jurisdiction of this case under the Declaratory Judgment Act.

IV. CONCLUSION

For the reasons described above, Defendant's motion to dismiss the Amended Complaint is **DENIED**. (ECF No. 27.) In their briefs in support of their litigation positions, both parties argued for opposing interpretations of the Advil II Order. Neither party, however, has moved for a judgment on the pleadings. The Court therefore schedules a status conference on

January 6, **2016 at** 10 :30 a **.m.** to discuss how the parties wish to proceed. Counsel for the parties should report to Courtroom 1306 at the Thurgood Marshall U.S. Courthouse, 40 Foley Square, New York, NY 10007.

SO ORDERED.

Dated: December 11, 2015
New York, New York

Andrew L Carter Jr

ANDREW L. CARTER, JR.
United States District Judge